

# **EXHIBIT 44**

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<div>UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA</div> <div>-----</div> <div>In Re: Bair Hugger Forced Air Warming Products Liability Litigation</div> <div>This Document Relates To: All Actions MDL No. 15-2666 (JNE/FLM)</div> <div>-----</div> <div>DEPOSITION OF JONATHAN BORAK VOLUME I, PAGES 1 - 251 JULY 20, 2017</div> <div>(The following is the deposition of JONATHAN BORAK, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 8:09 o'clock a.m., July 20, 2017.)</div>	<div>INDEX</div> <table><thead><tr><th>EXHIBITS</th><th>DESCRIPTION</th><th>PAGE MARKED</th></tr></thead><tbody><tr><td>Ex 1</td><td>Expert report of Jonathan Borak</td><td></td></tr><tr><td></td><td>Borak</td><td>7</td></tr><tr><td>2</td><td>Borak curriculum vitae</td><td>8</td></tr><tr><td>3</td><td>Jonathan Borak &amp; Company website download</td><td>39</td></tr><tr><td>4</td><td>Article, Mortality Disparities in Appalachia, by Borak, et al</td><td>46</td></tr><tr><td>5</td><td>E-mail sent September 06, 2002</td><td>54</td></tr><tr><td>6</td><td>Exhibit B to Borak's expert report</td><td>61</td></tr><tr><td>7</td><td>Kurz deposition excerpt, January 12, 2017</td><td>76</td></tr><tr><td>8</td><td>E-mail, 3M00580475</td><td>90</td></tr><tr><td>9</td><td>510(k) Summary of Safety &amp; Effectiveness, January 10, 1996, 3MBH00047382-3</td><td>94</td></tr><tr><td>10</td><td>E-mail string, 3MBH00024633-4</td><td>113</td></tr><tr><td>11</td><td>E-mail string, 3MBH00544754-5</td><td>119</td></tr><tr><td>12</td><td>E-mail string, 3MBH00132501-2</td><td>124</td></tr><tr><td>13</td><td>E-mail string, 3MBH00130429-32</td><td>126</td></tr><tr><td>14</td><td>E-mail string, 3MBH01330587-92</td><td>128</td></tr><tr><td>15</td><td>Article, Return to theatre following total hip and knee</td><td></td></tr></tbody></table>	EXHIBITS	DESCRIPTION	PAGE MARKED	Ex 1	Expert report of Jonathan Borak			Borak	7	2	Borak curriculum vitae	8	3	Jonathan Borak & Company website download	39	4	Article, Mortality Disparities in Appalachia, by Borak, et al	46	5	E-mail sent September 06, 2002	54	6	Exhibit B to Borak's expert report	61	7	Kurz deposition excerpt, January 12, 2017	76	8	E-mail, 3M00580475	90	9	510(k) Summary of Safety & Effectiveness, January 10, 1996, 3MBH00047382-3	94	10	E-mail string, 3MBH00024633-4	113	11	E-mail string, 3MBH00544754-5	119	12	E-mail string, 3MBH00132501-2	124	13	E-mail string, 3MBH00130429-32	126	14	E-mail string, 3MBH01330587-92	128	15	Article, Return to theatre following total hip and knee	
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<div>1 APPEARANCES:</div> <div>2 On Behalf of the Plaintiffs:</div> <div>3 Jan M. Conlin</div> <div>4 CIRESI CONLIN L.L.P.</div> <div>5 225 South 6th Street, Suite 4600</div> <div>6 Minneapolis, Minnesota 55402</div> <div>7 On Behalf of Defendants:</div> <div>8 Corey L. Gordon</div> <div>9 BLACKWELL BURKE P.A.</div> <div>10 431 South Seventh Street, Suite 2500</div> <div>11 Minneapolis, Minnesota 55415</div> <div>12 ALSO APPEARING:</div> <div>13 Ronald M. Huber, Videotechnician</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>1 replacement, before and after</div> <div>2 the introduction of rivaroxaban,</div> <div>3 by Jensen, et al 145</div> <div>4 16 Article in Health Devices,</div> <div>5 Force-Air Warming and</div> <div>6 Surgical Site Infections 154</div> <div>7 17 Article, Wound Complications</div> <div>8 Following Rivaroxaban Administra-</div> <div>9 tion, by Jameson, et al 154</div> <div>10 18 Reed deposition transcript,</div> <div>11 December 4, 2016 161</div> <div>12 19 Article, Chlorhexidine-Alcohol</div> <div>13 versus Povidone-Iodine for</div> <div>14 Surgical-Site Antisepsis, by</div> <div>15 Darouiche, et al 170</div> <div>16 20 Article, Preventing Surgical-</div> <div>17 Site Infections in Nasal</div> <div>18 Carriers of Staphylococcus</div> <div>19 aureus, by Bode, et al 175</div> <div>20 21 Article, Effects of preoperative</div> <div>21 warming on the incidence of</div> <div>22 wound infection after clean</div> <div>23 surgery: A randomised controlled</div> <div>24 trial, by Melling, et al 190</div> <div>25 22 Article, Prophylactic antibiotics</div>																																																			

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<p>1 correct?</p> <p>2 <b>A. It was my opinion that the man's cigarette</b></p> <p>3 <b>smoking and long history that predated the World Trade</b></p> <p>4 <b>Center explained his complaints.</b></p> <p>5 Q. Okay. And what was your -- subject matter</p> <p>6 of your testimony in Cabot Corporation?</p> <p>7 <b>A. I -- I already alluded to that. That had to</b></p> <p>8 <b>do with the adjudication in terms of the insurance</b></p> <p>9 <b>coverage for -- between two companies.</b></p> <p>10 Q. And what was the particular chemical of</p> <p>11 concern?</p> <p>12 <b>A. The issue had to do with if one could get</b></p> <p>13 <b>coal miner's pneumoconiosis in the absence of silica.</b></p> <p>14 Q. And in that case you concluded that the --</p> <p>15 that he can't; correct?</p> <p>16 (Discussion off the stenographic record.)</p> <p>17 <b>A. Yes. My conclusion was that the absence of</b></p> <p>18 <b>silica, that -- no, let me turn it the other way --</b></p> <p>19 <b>that the presence of silica contributed to the</b></p> <p>20 <b>formation of pneumoconiosis.</b></p> <p>21 Q. Okay. And how about in the final case,</p> <p>22 Secretary of Labor (MSHA) versus Klondex Midas, which</p> <p>23 side were you on in this case?</p> <p>24 <b>A. I -- I was involved with Klondex Midas, and</b></p> <p>25 <b>the case concerned whether medical causes of loss of</b></p>	<p>1 question.</p> <p>2 <b>A. I -- I don't object to his use of the</b></p> <p>3 <b>sufficient component cause model. I raise concerns at</b></p> <p>4 <b>the end of this section of my report and we could</b></p> <p>5 <b>address that specifically. Now it's not only the</b></p> <p>6 <b>conclusion, there was something in the method that I</b></p> <p>7 <b>had a problem with.</b></p> <p>8 Q. Okay. But the sufficient component</p> <p>9 causation methodology is well established and accepted</p> <p>10 amongst epidemiologists.</p> <p>11 <b>A. I -- I think probably. I -- I don't --</b></p> <p>12 <b>I'm not objecting to that.</b></p> <p>13 Q. Okay. And in fact you went through the same</p> <p>14 framework in connection with responding to Dr. Samet's</p> <p>15 report; correct?</p> <p>16 <b>A. Well I probably would have done that to be</b></p> <p>17 <b>responsive to Dr. Samet. I don't know if I would have</b></p> <p>18 <b>done it otherwise.</b></p> <p>19 Q. Okay. But you did in fact use the same</p> <p>20 framework. You didn't employ a different framework --</p> <p>21 <b>A. No. No.</b></p> <p>22 Q. -- in connection with responding; correct?</p> <p>23 <b>A. Yes, that's correct I think.</b></p> <p>24 Q. Okay. Would you agree with me that when</p> <p>25 you're looking at epidemiology, that drawing causal</p>
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<p>1 <b>consciousness had been addressed and considered by a</b></p> <p>2 <b>coroner and others.</b></p> <p>3 Q. And what did you opine in that case?</p> <p>4 <b>A. I agreed with statements from the coroner</b></p> <p>5 <b>that she had not looked for such causes and could not</b></p> <p>6 <b>render such an opinion.</b></p> <p>7 Q. Now you talk in your expert report about</p> <p>8 sufficient component causation; correct?</p> <p>9 <b>A. Yes. I think I spoke to it in the context</b></p> <p>10 <b>of Dr. Samet's report.</b></p> <p>11 Q. Right. And you'd agree with me that it's a</p> <p>12 well accepted methodology in epidemiological studies;</p> <p>13 correct?</p> <p>14 <b>A. I accept the concept.</b></p> <p>15 Q. Yeah. And in fact it was first espoused by</p> <p>16 Dr. Rothman; correct?</p> <p>17 <b>A. I looked at it in Dr. Rothman's writings as</b></p> <p>18 <b>a result of Dr. Samet citing that, yes.</b></p> <p>19 Q. And you'd agree with me Dr. Rothman is one</p> <p>20 of the leading minds in epidemiology.</p> <p>21 <b>A. I think Dr. Rothman is a leading mind in</b></p> <p>22 <b>epidemiology.</b></p> <p>23 Q. So you don't take issue with Dr. Samet's</p> <p>24 methodology, just his conclusions; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p>1 inferences after finding association requires</p> <p>2 judgment?</p> <p>3 <b>A. Judgment is part of the requirements, yes.</b></p> <p>4 Q. Okay. Would you agree with me that although</p> <p>5 the drawing of causal inferences is informed by</p> <p>6 scientific expertise, it is not a determination that</p> <p>7 is made using an objective or algorithm -- algorithmic</p> <p>8 methodology?</p> <p>9 <b>A. It is not necessarily.</b></p> <p>10 Q. What do you mean by "it is not necessarily."</p> <p>11 <b>A. Well read me back your question and I'll</b></p> <p>12 <b>answer your second question. You asked me do I agree</b></p> <p>13 <b>that it is not, and I -- my answer was it was not</b></p> <p>14 <b>necessarily.</b></p> <p>15 Q. Okay. Would you agree, quote, "Although the</p> <p>16 drawing of a causal in" -- strike that. Let me start</p> <p>17 over.</p> <p>18 Would you agree with me, quote, "Although</p> <p>19 the drawing of causal inferences is informed by</p> <p>20 scientific expertise, it is not a determination that</p> <p>21 is made using an objective or algorithmic</p> <p>22 methodology," end quote?</p> <p>23 <b>A. Yes. It is not necessarily based upon such</b></p> <p>24 <b>an algorithmic approach.</b></p> <p>25 Q. Would you agree with me that, quote,</p>

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<p style="text-align: right;">Page 69</p> <p>1 "Deciding whether associations are causal is not a 2 matter of statistics but a matter of good scientific 3 judgment and the questions that should be asked with 4 respect to the data offered?" 5 <b>A. In principle. But there are some terms in 6 that sentence which are difficult to define, such as 7 "good." "Good judgment" I think was the word.</b> 8 Q. Good scientific judgment. 9 <b>A. Good scientific judgment. I don't know 10 quite what that means. But I can understand the 11 sentence.</b> 12 Q. Well would you agree with me that The 13 Reference Guide on Statistics authored by Drs. Kay and 14 Friedman is an authoritative work? 15 <b>A. It's a reference that I refer to.</b> 16 Q. Okay. And you rely on it; right? 17 <b>A. I do.</b> 18 Q. And you don't take issue with what Drs. Kay 19 and Friedman have written in connection with The 20 Reference Guide on Statistics. In fact, you've relied 21 on it; correct? 22 <b>A. That's correct.</b> 23 Q. I'd like to direct your attention, sir, to 24 paragraph -- or page three of your expert report in 25 this case, Borak Exhibit No. 1. Do you have that in</p>	<p style="text-align: right;">Page 71</p> <p>1 of SSI." 2 <b>A. Yes, I said that.</b> 3 Q. Okay. I take it that you think the CDC in 4 terms of -- 5 You know, let me strike that and ask it a 6 different way. 7 You relied on the CDC guidelines here in 8 connection with your report; correct? 9 <b>A. I -- I cited it, yes.</b> 10 Q. Okay. And you relied on it. 11 <b>A. Well I relied upon it as an example of a 12 statement from a well-regarded organization, yes.</b> 13 Q. Okay. And you agree the CDC is well- 14 regarded; correct? 15 <b>A. Generally, yes.</b> 16 Q. Okay. In connection with your work over the 17 course of your career, your emphasis has been on 18 exposure to environmental toxins as opposed to 19 infectious agents; correct? 20 <b>A. For the most part.</b> 21 Q. Have you ever opined in a case that involved 22 not an environmental toxin but an infectious agent? 23 <b>A. Years ago, when I ran a trauma center, I was 24 involved in litigation that involved malpractice kinds 25 of issues, clinical malpractice issues, and I can</b></p>
<p style="text-align: right;">Page 70</p> <p>1 front of you? 2 <b>A. I do.</b> 3 Q. Okay. And I'd like to direct your attention 4 to Roman No. II, "The Samet Report." In 11a you talk 5 about this notion that there is sufficient evidence 6 that warming surgical patients to prevent hypothermia 7 and maintain normothermia reduces the rates of SSI; 8 correct? 9 <b>A. Correct.</b> 10 Q. And you cite to the CDC's guideline as one 11 of your references; correct? 12 <b>A. Yes.</b> 13 Q. And the World Health Organization; correct? 14 <b>A. Yes.</b> 15 Q. Okay. Did you investigate what -- what 16 information either the CDC or WHO had in connection 17 with their suggestion and determination that warming 18 is important? 19 <b>A. Well I -- I've read the documents and I've 20 looked at some of the references. Is that an answer 21 to your question?</b> 22 Q. Okay. And you say in the next paragraph, 23 "In addition, published findings from two random 24 control trials document that use of Bair Hugger to 25 maintain intraoperative normothermia reduced the risk</p>	<p style="text-align: right;">Page 72</p> <p>1 <b>remember in that context there were questions that 2 arose regarding infections. But that would have been 3 some time ago.</b> 4 Q. Well you were a participant. It was part 5 of -- 6 I mean you were involved in that case as a 7 result of your work; correct? 8 <b>A. No, no. I was an expert in that context.</b> 9 Q. When was that? 10 <b>A. Oh, it --</b> 11 <b>There were more than one, and it would have 12 been before 1990 because before -- in 1990 I 13 essentially separated myself from my emergency 14 practice, and during the time between 1980 and 1990, 15 approximately, I was involved in a fairly large number 16 of litigation questions, often only from the 17 standpoint of looking at medical records and saying 18 whether I thought there was or was not some kind of a 19 problem, and in that context, some of those involved 20 infectious diseases.</b> 21 Q. Have you ever been retained, litigation or 22 non-litigation, to provide an epidemiological opinion 23 that relates to an infectious organism? 24 <b>A. I did some work several years ago at the 25 interface of epidemiology and occupational medicine</b></p>

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<p style="text-align: right;">Page 145</p> <p>1 for infection than Xarelto.</p> <p>2 <b>A. I understand that tinza -- tinzap --</b></p> <p>3 <b>trinzaparin -- I don't know how to say it, but I</b></p> <p>4 <b>believe it's trinzaparin -- I believe that it is</b></p> <p>5 <b>associated with less wound bleeding postoperatively.</b></p> <p>6 Q. We'll just go there. Hold on.</p> <p>7 (Exhibit 15 was marked for</p> <p>8 identification.)</p> <p>9 THE WITNESS: Thank you.</p> <p>10 BY MS. CONLIN:</p> <p>11 Q. I've handed you what's been marked as Borak</p> <p>12 Deposition Exhibit 15, which is an article entitled</p> <p>13 "Return to the surgery following total hip and knee</p> <p>14 replacement, before and after the introduction of</p> <p>15 rivaroxaban." Do you see that?</p> <p>16 <b>A. I do.</b></p> <p>17 Q. And the rivaroxaban is Xarelto; correct?</p> <p>18 <b>A. I believe so.</b></p> <p>19 Q. Okay. And is this the study that you're</p> <p>20 referencing?</p> <p>21 <b>A. I believe it is. I've looked at it in a</b></p> <p>22 <b>different format, so it's --</b></p> <p>23 <b>It was a pdf, printed in a different format,</b></p> <p>24 <b>but I think it's correct.</b></p> <p>25 Q. Okay. Do you see the third author listed</p>	<p style="text-align: right;">Page 147</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 Q. You haven't done an investigation beyond</p> <p>4 what you -- what you've read; correct?</p> <p>5 <b>A. I have not directly studied the use of</b></p> <p>6 <b>Xarox -- Xarelto.</b></p> <p>7 Q. Okay. What investigation did you do other</p> <p>8 than read the couple of articles that are cited in</p> <p>9 your report?</p> <p>10 <b>A. Well I've read a lot of articles. Only</b></p> <p>11 <b>those cited are the ones I specifically was relying</b></p> <p>12 <b>upon. I don't want to diminish the effort that was</b></p> <p>13 <b>put into it, but I read the literature.</b></p> <p>14 Q. Okay. With respect to this issue of Xarelto</p> <p>15 being a potential confounder --</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. -- for the risk of infection in knee and hip</p> <p>18 surgeries, what other articles do you have in mind</p> <p>19 other than those that you cited in your report?</p> <p>20 <b>A. I think at the moment those are the ones</b></p> <p>21 <b>specifically that I would name.</b></p> <p>22 Q. And to the extent that Dr. Reed, an author</p> <p>23 of this study, said that this study proves that</p> <p>24 Xarelto is not a confounder in knee and hip surgery,</p> <p>25 you would disagree with him.</p>
<p style="text-align: right;">Page 146</p> <p>1 there?</p> <p>2 <b>A. Is it Partington?</b></p> <p>3 Q. No, that would be the -- well do you see --</p> <p>4 I guess it would be the fourth then. Do you</p> <p>5 see the fourth author there?</p> <p>6 <b>A. Dr. Reed.</b></p> <p>7 Q. Okay. Are you aware that Dr. Reed testified</p> <p>8 that this study showed no --</p> <p>9 Well strike it. Let me ask it a different</p> <p>10 way.</p> <p>11 Are you aware that Dr. Reed testified that</p> <p>12 this study eliminates Xarelto as a confounder for</p> <p>13 infection risks in knee and hip surgeries?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. I'm --</b></p> <p>17 <b>I don't remember that he said that, but I</b></p> <p>18 <b>think it's wrong.</b></p> <p>19 Q. Okay. So you don't remember reading it, but</p> <p>20 if he said it, he's wrong.</p> <p>21 <b>A. I believe it does not eliminate it. Yes,</b></p> <p>22 <b>that's correct.</b></p> <p>23 Q. Okay. And he's somebody who has</p> <p>24 investigated this issue. You're somebody who has read</p> <p>25 some articles. Correct?</p>	<p style="text-align: right;">Page 148</p> <p>1 <b>A. Did he say that here?</b></p> <p>2 Q. He said it in his deposition. I'm</p> <p>3 representing that to you.</p> <p>4 <b>A. I -- I don't think that this study</b></p> <p>5 <b>eliminates rivaroxaban as a confounder in the McGowan</b></p> <p>6 <b>study.</b></p> <p>7 Q. Okay. Based on what is my question.</p> <p>8 <b>A. Based on the fact that there was a</b></p> <p>9 <b>significant increase -- there was a large increase, I</b></p> <p>10 <b>think 2.5-to-one increase in infection rates, and I</b></p> <p>11 <b>think this study under-ascertained cases because it</b></p> <p>12 <b>only had a 30-day followup.</b></p> <p>13 Q. Well so you relied on it but you didn't rely</p> <p>14 on it?</p> <p>15 <b>A. No, no, no, no, no. I didn't rely upon it.</b></p> <p>16 <b>I said I think it did not prove that it was not a</b></p> <p>17 <b>confounder. Moreover, a confounder -- whether</b></p> <p>18 <b>something is or is not a confounder is not dependent</b></p> <p>19 <b>on whether it is, on a univariate level, statistically</b></p> <p>20 <b>significantly associated with the outcome or whether</b></p> <p>21 <b>it significantly influences the relationship that it</b></p> <p>22 <b>confounds.</b></p> <p>23 Q. It has to have an association.</p> <p>24 <b>A. That's a start but not a finish.</b></p> <p>25 MS. CONLIN: Okay. So why don't you pull</p>

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<p style="text-align: right;">Page 149</p> <p>1 out, Mr. Stirewalt, what was marked yesterday as</p> <p>2 Exhibit 19, because I think that is probably the pdf</p> <p>3 that he's used to seeing in connection with this</p> <p>4 study.</p> <p>5 <b>A. Maybe that one.</b></p> <p>6 <b>(Holford Exhibit 19 handed to the witness.)</b></p> <p>7 Q. I've handed you what's previously been</p> <p>8 marked as Holford Exhibit 19, which is, I believe, the</p> <p>9 same study in a different format. Is this the format</p> <p>10 that you're used to seeing this study?</p> <p>11 <b>A. Yes, that's correct.</b></p> <p>12 Q. Okay. And did you understand this study to</p> <p>13 be breaking down wound complications such as surgical</p> <p>14 wound infections versus deep joint infections?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 <b>A. You're asking me whether it specifically</b></p> <p>18 <b>differentiated different kinds of wound infections?</b></p> <p>19 Q. Deep joint versus a superficial wound</p> <p>20 infection or the like. Did you have that in mind when</p> <p>21 you reviewed this?</p> <p>22 <b>A. I don't recall having that particular</b></p> <p>23 <b>question in mind, --</b></p> <p>24 Q. Okay.</p> <p>25 <b>A. -- but I will -- would again if you'd like</b></p>	<p style="text-align: right;">Page 151</p> <p>1 that?</p> <p>2 <b>A. I'm sorry, let me try and read it more</b></p> <p>3 <b>clearly. I'm not seeing it well enough in this print.</b></p> <p>4 <b>Yes. Okay, I see that.</b></p> <p>5 Q. Okay. And do you see the p-value of .7?</p> <p>6 <b>A. .7 had to do with the probability that there</b></p> <p>7 <b>was a difference in the rate of deep versus</b></p> <p>8 <b>superficial infections.</b></p> <p>9 Q. My question is: Do you see the p-value of</p> <p>10 .7?</p> <p>11 <b>A. Yes, I see it.</b></p> <p>12 Q. Is that statistically significant?</p> <p>13 <b>A. No.</b></p> <p>14 Q. Okay. Then it says, "The overall rate of</p> <p>15 deep infection in group 1 was 1 percent (95) compared</p> <p>16 with 2.5 percent in group 2," p-value of .102, do you</p> <p>17 see that?</p> <p>18 <b>A. I do.</b></p> <p>19 Q. Is that statistically significant?</p> <p>20 <b>A. It is not.</b></p> <p>21 Q. Did you take that into account in connection</p> <p>22 with your conclusions in this case that Xarelto is a</p> <p>23 confounding factor for risk of infection?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>
<p style="text-align: right;">Page 150</p> <p>1 <b>me to.</b></p> <p>2 Q. Did you have it in mind when you rendered</p> <p>3 your opinions in this case on June 2nd?</p> <p>4 <b>A. Whether --</b></p> <p>5 <b>The differentiation between the types of</b></p> <p>6 <b>wound infections?</b></p> <p>7 Q. Correct.</p> <p>8 <b>A. I -- I'm sorry, and I'm just backing up. Is</b></p> <p>9 <b>that raised in this document? It would help me to</b></p> <p>10 <b>reconstruct and answer your question.</b></p> <p>11 Q. Well I'm just asking if you had it in mind</p> <p>12 when you --</p> <p>13 <b>A. I'm sure I had it somewhere in mind, but I</b></p> <p>14 <b>don't remember whether it was relevant, that question,</b></p> <p>15 <b>to this article.</b></p> <p>16 Q. Okay. Why don't you take a look at</p> <p>17 intern -- page 523, which is the third page of this</p> <p>18 study, under "Results," and I'd like to direct your</p> <p>19 attention down to the third paragraph starting with</p> <p>20 "Of those patients who returned to theatre,</p> <p>21 microbiology results showed that five of the nine</p> <p>22 (55.5 percent) in group 1 had a deep infection,</p> <p>23 compared with 14 of 22 (63.6 percent) in group 2."</p> <p>24 <b>A. Okay.</b></p> <p>25 Q. And it's got a p-value of .7, do you see</p>	<p style="text-align: right;">Page 152</p> <p>1 <b>A. It's discussed in paragraph 42 and following</b></p> <p>2 <b>in my report.</b></p> <p>3 Q. My question is a little different. Did you</p> <p>4 take that into account in connection with your</p> <p>5 conclusions in this case?</p> <p>6 <b>A. And I'm showing you, yes, I took it into</b></p> <p>7 <b>account --</b></p> <p>8 Q. Okay.</p> <p>9 <b>A. -- in paragraphs 42 and following in my</b></p> <p>10 <b>report.</b></p> <p>11 Q. I think I asked you this before, but in</p> <p>12 connection -- you didn't --</p> <p>13 You didn't actually look at the mathematical</p> <p>14 work Professor Holford did in reanalyzing the McGovern</p> <p>15 data with Jensen; correct?</p> <p>16 MR. GORDON: Objection.</p> <p>17 <b>A. Yes, I did not.</b></p> <p>18 Q. Okay. And to the extent that he used either</p> <p>19 data from Albrecht Exhibit 10 or McGovern Exhibit 16,</p> <p>20 you would be deferring to him as to the</p> <p>21 appropriateness of that; correct?</p> <p>22 <b>A. Yes, I would.</b></p> <p>23 Q. Now I'd like to talk to you a little bit</p> <p>24 about the Hawthorne effect and -- which is contained</p> <p>25 on page 16 of your report. Wouldn't --</p>

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1 Well first of all, wouldn't the Hawthorne  
2 effect exist in any observational study?

3 **A. I think it depends upon whether the subjects**  
4 **are aware of the observation and how intensively the**  
5 **observation impacts the daily life of those**  
6 **individuals.**

7 Q. Well do you know whether any of the  
8 participants in the Reed and McGovern study were  
9 involved, that there was a study going on?

10 **A. I -- I understand from the statements that**  
11 **were made in the citation which I cited -- "citation**  
12 **which I cited" sounds like a redundancy -- there was**  
13 **an award given to Northumbria, and in the context of**  
14 **that they cited the efforts that had gone into it.**  
15 **There's also description of the change in the**  
16 **sensibility that was engendered as described by**  
17 **Gillson and Lowdon or something, and my understanding**  
18 **is that there was a full-court press to try to change**  
19 **the behavior of the people, which included changing**  
20 **clothes and changing the manner in which the clothes**  
21 **were stored and changing shoes, and a variety of other**  
22 **things were done, and I think that everybody there was**  
23 **very aware that there was a problem with infections.**

24 Q. My question was a little different.

25 **A. Okay. I'm sorry.**

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1 Q. -- which is the Jameson study entitled  
2 "Wound Complications Following Rivaroxaban  
3 Administration." This is one of the documents that  
4 you referenced and opined on in your report; correct?

5 **A. That's correct.**

6 Q. Okay. In connection with your review, did  
7 you have in mind a difference or -- between a deep  
8 joint infection and a superficial or deep tissue  
9 infection?

10 **A. I don't think it was defined clearly in this**  
11 **paper, and so I don't think that I made a decision.**  
12 **But --**

13 Q. Okay. Would it be important in connection  
14 with making decisions that a change to Xarelto  
15 postoperatively as an antithrombotic prophylaxis  
16 increases the risk of a deep joint infection?

17 **A. I'm sorry, repeat that.**

18 Q. Sure. Would it be important in connection  
19 with making decisions in this case that a change in  
20 Xarelto postoperatively -- postoperatively as an  
21 antithrombotic prophylaxis increases the risk of a  
22 deep joint infection as opposed to another kind of  
23 wound infection?

24 **A. Would it matter to me? Yes, I would**  
25 **consider that. I --**

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1 Q. My question was: Do you believe that any of  
2 the participants' employees understood or were aware  
3 that there was going to be an observational study  
4 conducted and published regarding infections in knee  
5 and hip arthroplasty?

6 **A. I -- I have --**

7 MR. GORDON: Object to the form of the  
8 question.

9 **A. I have no idea if anybody at the time knew**  
10 **because the study was post hoc.**

11 **(Discussion off the stenographic record.)**  
12 **(Exhibit 16 was marked for**  
13 **identification.)**

14 THE WITNESS: Thank you.

15 BY MS. CONLIN:

16 Q. I have handed you, sir, what's been marked  
17 as Borak Deposition Exhibit 16, which is -- not what I  
18 wanted to give you. Hold on. You can set that aside,  
19 I'll get back to that.

20 **(Exhibit 17 was marked for**  
21 **identification.)**

22 BY MS. CONLIN:

23 Q. I have handed you, sir, what's been marked  
24 as Borak Deposition Exhibit 17, --

25 **A. Yes.**

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1 **Would you point to what you are talking**  
2 **about in the paper so I understand the context of your**  
3 **question?**

4 Q. Well I'm just under --

5 I'm trying to understand your opinion, sir,  
6 when you say that the change in -- from rivar -- or  
7 from trinzaparin to Xarelto creates an increased risk  
8 of a deep joint infection, that you had paid attention  
9 in the papers that you were citing as to differences  
10 between, for example, a superficial wound or a deep  
11 wound infection and a deep joint infection.

12 **A. I'm sorry, I -- I cited this paper for a**  
13 **different reason, not to suggest what you are asking.**  
14 **I cited it because Dr. Samet had cited it, and Dr.**  
15 **Samet had cited it as evidence that it did not create**  
16 **a difference.**

17 Q. My question was: When you opine that a  
18 change from trinzaparin to Xarelto creates an  
19 increased risk of deep joint infection, did you pay  
20 attention in the papers that you were citing as to the  
21 differences between, for example, superficial wound or  
22 deep wound or a deep joint infection?

23 **A. Let me answer, yes, I was aware of the**  
24 **difference.**

25 Q. Do you think that you can extrapolate from

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<p style="text-align: right;">Page 197</p> <p>1 something else?</p> <p>2 <b>A. That is the one that has been used almost</b></p> <p>3 <b>universally, so I -- I am reasonably certain that I --</b></p> <p>4 <b>I would have expected that. And I thought I knew</b></p> <p>5 <b>that, but at the moment sitting here I can't point to</b></p> <p>6 <b>a place where I found that specific detail.</b></p> <p>7 Q. And you again, in connection with this MSSA</p> <p>8 screening, rely on statements by Dr. Reed; correct?</p> <p>9 <b>A. Well I pointed to Dr. Reed's statement.</b></p> <p>10 Q. Well you relied on it; correct?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. Okay.</p> <p>13 <b>A. Oh, okay. There. Okay. So it is Dr. Reed</b></p> <p>14 <b>who literally there said, "After MSSA screening, a</b></p> <p>15 <b>decolonization was introduced," and I took for granted</b></p> <p>16 <b>that that was referring to this time in this study of</b></p> <p>17 <b>concern that we have with McGovern.</b></p> <p>18 Q. Okay. Did you do any analysis as to whether</p> <p>19 MSSA infections went up after MSSA screening and</p> <p>20 decolonization was implemented in January 2010?</p> <p>21 <b>A. I understand from conversations -- I did not</b></p> <p>22 <b>look at the raw data -- that there were none reported</b></p> <p>23 <b>after the introduction of that process.</b></p> <p>24 Q. So you would disagree that there was an</p> <p>25 uptick in infections after MSSA screening was</p>	<p style="text-align: right;">Page 199</p> <p>1 MR. GORDON: Dotted green or blue?</p> <p>2 MS. CONLIN: Well whatever. It's the one</p> <p>3 dotted line with the circle.</p> <p>4 Q. Do you see that?</p> <p>5 <b>A. Yes.</b></p> <p>6 MS. CONLIN: Okay. And yeah, it does look</p> <p>7 blue, Mr. Gordon. Thank you. We'll refer to it as</p> <p>8 the dotted blue line.</p> <p>9 Q. You'll see that there's a reference point</p> <p>10 there of September 2008.</p> <p>11 Right here.</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Okay. And then if you look, based on this</p> <p>14 graph, MSSA infections went down between September</p> <p>15 2008 and October 2009; correct?</p> <p>16 <b>A. It seems to be.</b></p> <p>17 Q. Okay. And then after October 2009 to</p> <p>18 November 2011, you'll see there's an uptick; correct?</p> <p>19 <b>A. I do see that.</b></p> <p>20 Q. Okay. Is that something that you</p> <p>21 investigated in connection with your view that the</p> <p>22 MSSA screening renders the McGov -- is a confounder to</p> <p>23 the McGovern report?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>
<p style="text-align: right;">Page 198</p> <p>1 implemented?</p> <p>2 <b>A. I thought that there were no MSSA</b></p> <p>3 <b>infections.</b></p> <p>4 <b>(Exhibit 24 was marked for</b></p> <p>5 <b>identification.)</b></p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Borak Deposition Exhibit 24, which is a document</p> <p>9 entitled "Surveillance of surgical site infections in</p> <p>10 NHS hospitals in England." Do you see that?</p> <p>11 <b>A. I do.</b></p> <p>12 Q. Okay. And is this something you've seen</p> <p>13 before?</p> <p>14 <b>A. I have seen documents that look like this.</b></p> <p>15 <b>I don't know if this is the one I saw.</b></p> <p>16 Q. Okay. If we can direct your attention to</p> <p>17 page 30, --</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. -- Figure 11, "Trends in micro-organisms</p> <p>20 reported as causing inpatient SSIs, proportions with</p> <p>21 lower and upper 95 percent confidence, all surgical</p> <p>22 categories, NHS hospitals, England." Do you see that?</p> <p>23 <b>A. I do.</b></p> <p>24 Q. Okay. Now you'll see the dotted green line</p> <p>25 is MSSA infections; correct?</p>	<p style="text-align: right;">Page 200</p> <p>1 <b>A. I would not have looked at this since this</b></p> <p>2 <b>is a composite of all of the hospitals in England -- I</b></p> <p>3 <b>think it is all of them -- and it is all forms of</b></p> <p>4 <b>surgery, and so I'm not quite sure what one could have</b></p> <p>5 <b>drawn from this or what it would have told me other</b></p> <p>6 <b>than the fact that there was heterogeneity in the</b></p> <p>7 <b>operating room procedures in the NHS hospitals.</b></p> <p>8 Q. Do you know which hospitals were included in</p> <p>9 this?</p> <p>10 <b>A. I'm happy to look at the beginning.</b></p> <p>11 Q. Well you just said it includes all the</p> <p>12 hospitals. I'm wondering if you know that or you're</p> <p>13 just assuming that.</p> <p>14 <b>A. I am assuming it based upon what I saw in a</b></p> <p>15 <b>quick look at the document, but I'm happy to look</b></p> <p>16 <b>further. "Since July 2008 hospitals were required" --</b></p> <p>17 <b>I mean I'm happy to take time to look for</b></p> <p>18 <b>the number, but --</b></p> <p>19 Q. No. I -- I was just curious, when you said</p> <p>20 that it included more hospitals than the three at</p> <p>21 issue in McGovern, whether you knew that or you were</p> <p>22 just speculating.</p> <p>23 <b>A. Oh, no, no, no, I'm not speculating, but I</b></p> <p>24 <b>don't know what the number is.</b></p> <p>25 Q. Okay.</p>

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<p>1       <b>A. This is a composite of the NHS system. We</b>  2       <b>are looking at, in McGovern, one hospital.</b>  3       Q. Okay. But you --  4       Your view is that because the MSSA data on  5       that chart we just looked at isn't specific to deep  6       joint infections, it wouldn't be a fair comparison; is  7       that right?  8       <b>A. No. It wouldn't be a fair comparison</b>  9       <b>because it's looking at, I believe, most if not all of</b>  10       <b>the NHS hospitals in England. I don't know about</b>  11       <b>their implementation of procedures and protocols. I</b>  12       <b>believe I saw something here about a lack of</b>  13       <b>consistency in the applications of protocols. I think</b>  14       <b>there are a variety of other considerations. So I</b>  15       <b>wouldn't use this to inform my thinking about</b>  16       <b>Northumbria.</b>  17       Q. And one of the reasons that you just stated  18       that you didn't think it would be a fair comparison is  19       because it's including other surgeries, not just deep  20       joint infections; correct?  21       <b>A. Yes.</b>  22       Q. Other types of infections.  23       <b>A. Yes.</b>  24       Q. And you don't think it would be fair to  25       extrapolate from one type of infection in one part of</p>	<p>1       <b>(Exhibit 25 was marked for</b>  2       <b>identification.)</b>  3       BY MS. CONLIN:  4       Q. I've handed you, sir, what's been marked as  5       Borak Exhibit 25, which I think is your reference --  6       <b>A. I think it's number 30.</b>  7       Q. -- your reference number 30; correct?  8       <b>A. I believe that's correct.</b>  9       Q. Thank you. Okay. And this was one of the  10       things that you relied on to suggest that  11       decolonization with a topical antibiotic, mupirocin,  12       has been shown to significantly reduce risk of post-  13       surgical infections, including hip and knee  14       replacements; correct?  15       <b>A. Yes.</b>  16       Q. Okay. I'd like to direct your attention to  17       the third paragraph of this article.  18       <b>A. After the introduction or in the abstract?</b>  19       Q. Internal page 2385. Got a chart at the top.  20       <b>A. Third page. I thought you said paragraph.</b>  21       <b>Okay.</b>  22       Q. In the paragraph about "Of the 19  23       studies..."  24       <b>A. "Of the 19 studies..." Yes.</b>  25       Q. On the right-hand side, midway down, it</p>
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<p>1       the body to a deep joint infection even if it's MSSA;  2       correct?  3       <b>A. I -- I -- I --</b>  4       <b>Yes. I think this would raise the question</b>  5       <b>whether this added or altered my thinking, and I</b>  6       <b>referred ultimately to a comment which came literally</b>  7       <b>from Dr. Reed who said that "In the fight against</b>  8       <b>PJI" -- prosthetic joint infections -- "after MSSA</b>  9       <b>screening and decolonization was introduced, one NHS</b>  10       <b>joint replacement unit, the MSSA infection was reduced</b>  11       <b>from .84 to .26." I believe that is speaking about</b>  12       <b>Wansbeck, though in looking at the document I couldn't</b>  13       <b>tell which of the three hospitals it was, but I</b>  14       <b>presume it is because it's where there was the data.</b>  15       MS. CONLIN: Move to strike as non-  16       responsive.  17       Can you read my question back?  18       (Record read by the court reporter.)  19       <b>A. I -- I have difficulty extrapolating from</b>  20       <b>this document. I might also have --</b>  21       Q. I didn't ask you that. I asked you a  22       straight-up question.  23       MS. CONLIN: Could you read it back again.  24       (Record read by the court reporter.)  25       <b>A. It might not be fair.</b></p>	<p>1       says, "The majority of studies detected S. aureus  2       colonization using cultures, most SSIs were defined by  3       CDC criteria, the majority of studies did not  4       differentiate between superfer -- superficial versus  5       deep infections, and most of the patients who  6       underwent decolonization were positive for S. aureus  7       on nasal screens." Do you see that?  8       <b>A. I do.</b>  9       Q. In connection with your discussion of MSSA  10       screening, you bundled infections regardless of  11       whether they were deep joint infections; correct?  12       MR. GORDON: Object to the form of the  13       question.  14       <b>A. I cited a paper which I think may have</b>  15       <b>bundled it.</b>  16       Q. In -- in support of your belief that the  17       implementation of MSSA screening and decolonization is  18       a confounding factor in McGovern; correct?  19       <b>A. Yes. Correct.</b>  20       <b>(Exhibit 26 was marked for</b>  21       <b>identification.)</b>  22       THE WITNESS: Thank you.  23       BY MS. CONLIN:  24       Q. I've handed you what's been marked as Borak  25       Exhibit 26, which is a JAMA survey entitled "Centers</p>

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